



01-23-03

1637

PATENT
Attorney Docket No. 010211

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit No.: 2661 : PCR METHOD

In re application of: Godfrey *et al.* :

Serial No.: 10/090,326 :

Filing Date: March 4, 2002 :

#5
Plunkert
1/30/03

RECEIVED
JAN 27 2003
TECH CENTER 1600/2000

INFORMATION DISCLOSURE STATEMENT

Pittsburgh, Pennsylvania 15222

January 22, 2003

Commissioner for Patents

Washington, DC 20231

Sir:

Applicants, in accordance with their duty of disclosure pursuant to 37 C.F.R. § 1.56, hereby advise the United States Patent and Trademark Office of the references listed on the accompanying form PTO/SB/08A *Information Disclosure Statement* by Applicant. A copy of each of the references cited therein is herewith enclosed.

"Express Mail" mailing label number EU990147117US

Date of Deposit January 22, 2003

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.40 on the date indicated above and is addressed to the Commissioner for Patents, Washington, DC 20231.

Pursuant to 37 C.F.R. § 1.97(b)(3), no fee is due for the submission of this *Information Disclosure Statement*. The Commissioner is hereby authorized to charge any fees related to the filing of this *Information Disclosure Statement* to Deposit Account No. 11-1110.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J. Hirshman", is written over a horizontal line.

Jesse A. Hirshman
Registration No. 40,016

Attorney for Applicants

KIRKPATRICK & LOCKHART LLP
Henry W. Oliver Building
535 Smithfield Street
Pittsburgh, Pennsylvania 15222-2312
Telephone: (412) 355-8966
Facsimile: (412) 355-6501
E-mail: jhirshman@kl.com

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 2 of 4		Complete if Known	
		Application Number	10/090,326
		Filing Date	April 4, 2002
		First Named Inventor	Godfrey <i>et al.</i>
		Art Unit	
		Examiner Name	
		Attorney Docket Number	010211

RECEIVED
JAN 27 2003
CENTRAL
1600/2800

RECEIVED

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		GenBank Accession No. XM_012777 (SEQ ID NO: 1)	
		TaqMan One-Step RT-PCR Master Mix Reagents Kit, Protocol, <i>PE Biosystems</i> 1999.	
		Raja, S., Luketich, J.D., Ruff, D.W. and Godfrey, T.E., "Increased Sensitivity of One-Tube, Quantitative RT-PCR," <i>Bio Techniques</i> Vol. 29, No. 4:702-706 (October 2000)	
		ABI PRISM 7700 Sequence Detection System, User Bulletin #2, "Relative Quantitation of Gene Expression," <i>Applied Biosystems</i> (1997/updated 10/2001).	
		ABI PRISM 7700 Sequence Detection System, User Bulletin #5, "Multiplex PCR with TaqMan VIC Probes," <i>Applied Biosystems</i> (1998/updated 01/2001).	
		DeLong, E.R., DeLong, D.M. and Clarke-Pearson, D.L., "Comparing the areas under two or more correlated receiver operating characteristic curves: a nonparametric approach," <i>Biometrics</i> 44(3):837-845, 1988.	
		Gibson, U.E., Heid, C.A. and Williams, P.M. "A novel method for real time qualitative RT-PCR," <i>Genome Res</i> , 6:995-1001, 1996.	
		Heid, C.A., Stevens, J., Livak, K.J. and Williams, P.M., "Real time qualitative PCR," <i>Genome Res</i> , 6:986-994, 1996.	
		Davidson, A.C. and Hinkley, D.V., "Bootstrap Methods and Their Application," Cambridge, United Kingdom: <i>Cambridge University Press</i> , 1997.	
		Battaglia, M., Pedrazzoli, P., Palermo, B., Lanza, A., Bertonlini, F., Gibelli, N., Da Prada, G.A., Zambelli, A., <i>et al.</i> "Epithelial tumour cell detection and the unsolved problems of nested RT-PCR: a new sensitive one step method without false positive results," <i>Bone Marrow Transplant</i> 22:693-698, 1998.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 3 of 4		Complete if Known	
		Application Number	10/090,326
		Filing Date	April 4, 2002
		First Named Inventor	Godfrey et al.
		Art Unit	
		Examiner Name	
		Attorney Docket Number	010211

RECEIVED
JAN 27 2003
TEST CENTER 1600/1600

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		Collins, C., Rommens, J.M., Kowbel, D., Godfrey, T., Tanner, M., Hwang, S-I., Polikoff, D., Nonet, G., et al. "Positional cloning of ZNF217 and NABC1: Genes amplified at 20q13.2 and overexpressed in breast carcinoma. <i>Proc. Natl. Acad. Sci. USA</i> 95:8703-8708, 1998.	
		Fitzgerald RC, Triadafilopoulos G. "Recent Developments in the Molecular Characterization of Barrett's Esophagus." <i>Dig. Dis.</i> 16:63-80, 1998.	
		Liefers, G-J., Cleton-Jansen, A.M., Comelli, J.H., et al., R.A. "Micrometastases and survival in stage II colorectal cancer" [see comments]. <i>N. Engl. J. Med.</i> , 339: 223-228, 1998.	
		Shivers, S.C., Wang, X., Li, W., Joseph, E., Messina, J., Glass, L.F., DeConti, R., Cruse, C.W., Berman, C., Fenske, N.A., Lyman, G.H. and Reintgen, D.S., "Molecular Staging of Malignant Melanoma: Correlation with Clinical Outcome," <i>JAMA</i> , 280: 1410-1415, 1998.	
		Bostick, P.J., Morton, D.L., Turner, R.R., Huynh, K.T., Wang, H.J., Elashoff, R., Essner, R. and Hoon, D.S., "Prognostic Significance of Occult Metastases Detected by Sentinel Lymphadenectomy and Reverse Transcriptase-Polymerase Chain Reaction in Early-Stage Melanoma Patients," <i>J. Clin. Oncol.</i> , 17: 3238-3244, 1999.	
		Godfrey, T.E., Kim, S.-H., Chavira, M., Ruff, D.W., Warren, R.S., Gray, J.W. and Jensen, R.H. "Quantitative mRNA expression analysis from formalin-fixed, paraffin-embedded tissues using 5' nuclease quantitative RT-PCR," <i>J. Mol. Diagn.</i> , 2:84-91, 2000.	
		Heagerty, P.J., Lumley, T. and Pepe, M.S., "Time-Dependent ROC Curves for Censored Survival Data and a Diagnostic Marker," <i>Biometrics</i> , 56(2):337-845, 2000.	
		Tassone, F., Hagerman, R.J., Taylor A.K., Gane, L.W., Godfrey, T.E., and Hagerman, P.J., "Elevated Levels of FMR1 mRNA in carrier males: a new mechanism of involvement in the fragile-X syndrome," <i>Am. J. Hum. Genet.</i> , 66:6-15, 2000.	
		Weiser MR, Montgomery LL, Susnik B, Tan LK, Borgen PI, Cody HS. "Is routine intraoperative frozen-section examination of sentinel lymph nodes in breast cancer worthwhile?" <i>Ann Surg Oncol.</i> ; 7:651-655, 2000.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



RECEIVED
JAN 27 2003
PCH CENTER 1600

PTO/SB/08A/00-01

Approved for use through 10/31/2002. OMB 0652-0039

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 4 of 4		Complete if Known	
		Application Number	10/090,326
		Filing Date	April 4, 2002
		First Named Inventor	Godfrey et al.
		Art Unit	
		Examiner Name	
		Attorney Docket Number	010211

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		Godfrey TE, Raja S, Finkelstein SD, Kelly LA, Gooding W, Luketich JD. "Quantitative RT-PCR Predicts Disease Recurrence in lymph Node-Negative Esophagus Cancer Patients." <i>Proceedings from the 2001 Annual Meeting of the American Association of Cancer Researchers</i> 42. 3-1-2001.	
		Miyake, Y., Fujiwara, Y., Ohue, M., Yamamoto, H., Suita, Y., Tomita, N., Sekimoto, M., Shiozaki, H. and Monden, M. "Quantification of micrometastases in lymph nodes of colorectal cancer using real-time fluorescence polymerase chain reaction," <i>Int. J. Oncol.</i> 16(2):289-293 2000.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any information required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office. FOR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for